



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2010-0099; FRL-9337-3]

#### *Aureobasidium pullulans* strains DSM 14940 and DSM 14941; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in or on all food commodities when applied pre-harvest and used in accordance with good agricultural practices. Bio-ferm GmbH submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### **SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0099. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not made available via the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m.,

Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8077; e-mail address: *cerrelli.susanne@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at

*<http://ecfr.gpoaccess.gov/cgi/t/text/text->*

*[idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl)*. To access the harmonized test guidelines referenced in this document electronically, please go to

*<http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."*

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0099 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0099, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Background and Statutory Findings**

In the **Federal Register** of March 10, 2010 (75 FR 11171) (FRL-8810-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F7623) by Bio-ferm GmbH, Konrad Lorenz Str. 20, Tulln, 3430, Austria. The petition requested that 40 CFR part 180

be amended by establishing an exemption from the requirement of a tolerance for residues of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941. This notice referenced a summary of the petition prepared by the petitioner Bio-ferm GmbH, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider “available information concerning the cumulative effects of a particular pesticide's residues” and “other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### **III. Toxicological Profile**

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. *Overview of Aureobasidium pullulans strains DSM 14940 and DSM 14941*

*Aureobasidium pullulans* is a “yeast-like” saprophytic fungus found in the phyllosphere of many plants, and it has been isolated from soil and aquatic environments (Refs. 1, 2, and 3). It is commonly isolated from healthy grape (Refs. 4 and 5) and apple (Ref. 6) plants, as well as other plants (Refs. 7, 8, 9, 10, and 11). Although associated with disease in some plants, the fungus generally is recognized as a saprobe, since it derives its nourishment from nonliving or decaying organic matter, and is only considered a weak pathogen or parasite of certain plants (Refs. 2 and 12). It is a known antagonist of several plant disease-causing organisms, and is an important producer of enzymes for biotechnological and industrial applications (Ref. 1).

*Aureobasidium pullulans* strains DSM 14940 and DSM 14941 were isolated from apple leaves and classified by the German Strain Collection for Microorganisms (DSMZ). Neither is a mutant nor genetically modified strain and they are not closely related to toxigenic human pathogens. As discussed in Pesticide Petition (PP) 9F7623, product analysis data demonstrate that *Aureobasidium pullulans* strain DSM 14941 is closely related to strain DSM 14940. The two strains share many similar genetic and morphological characteristics. Bioferm GmbH has proposed to register two manufacturing-use pesticide products (MPs): “*Aureobasidium pullulans* strain DSM 14941 Technical,” and “*Aureobasidium pullulans* strain DSM 14940 Technical.” The active ingredient is 80% w/w (minimum of  $\times 10^9$  colony forming units/grams (unit of measure for bacteria (cfu/g)) in each of the proposed technical products.

Bio-ferm GmbH has proposed to register two end-use products (EPs) containing equal parts of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941: “Blossom Protect” will be applied to pome fruit only during the blossoming period to protect plants against bacterial fire blight, and “Botector” will be applied preharvest to grapes, pome fruit, stone fruit, and strawberries to protect these crops against fruit rot diseases caused by *Botrytis* sp., *Monilia* sp., *Penicillium* sp., *Nectria* sp., and *Pezicula* sp.

B. *Microbial Pesticide Toxicology Data Requirements*

The Agency has determined that, for preharvest uses, all mammalian toxicology data requirements submitted to support the petition to exempt residues of *Aureobasidium*

*pullulans* strains DSM 14940 and DSM 14941 from the requirement of a tolerance have been fulfilled (Ref. 13).

The product analysis data demonstrated that *Aureobasidium pullulans* strain DSM 14941 is closely related to strain DSM 14940. Because the strains are closely related, the Agency has determined that the findings of the submitted acute toxicity/pathogenicity studies conducted only with strain DSM 14941 supported both strains, and those studies show no evidence of toxicity, or pathogenicity at the doses tested. In addition, both strains were tested in an acute subcutaneous injection toxicity/pathogenicity study in rats. The results of this study indicated that both strains were not toxic, infective, and/or pathogenic to the test animals. These findings were supported by the results of a study of the influence of temperature on the growth of the two *Aureobasidium pullulans* strains, which showed that growth of both strains does not occur at or above 35 °C. Since human body temperature is 37 °C, and based on the results from these studies as discussed in this unit the Agency concluded that neither strain would be toxic, infective and/or pathogenic in humans.

1. *Acute Oral Toxicity/Pathogenicity (Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 885.3050; Master Record Identification Number (MRID) No. 47899302.* Twenty-four rats were administered a single dose of *Aureobasidium pullulans* strain DSM 14941. Three animals of each sex were sacrificed on days 3, 7, and 14; the remaining animals were sacrificed at test end on day 21. Body tissues were examined for *Aureobasidium pullulans*. All samples of feces, blood, brain, lung, liver, kidney, spleen, stomach, and intestine were negative. The lymph nodes of one animal sacrificed on day 7 tested positive for the presence of *Aureobasidium pullulans* DSM 14941. These findings show a pattern of clearance with no *Aureobasidium pullulans* DSM 14941 detected by day 14. The results of this acceptable study demonstrated that *Aureobasidium pullulans* DSM 14941 was not toxic, infective, and/or pathogenic in rats, when dosed at  $4 \times 10^8$  cfu/animal.

2. *Acute Pulmonary Toxicity/Pathogenicity (OCSPP Guideline 885.3150; MRID No. 47899303).* Male and female animals were exposed intratracheally with *Aureobasidium pullulans* strain DSM 14941 Technical ( $4 \times 10^8$  cfu/g). Interim sacrifices were made 3 hours post-dose and on study days 3, 7, and 14; the remaining animals were

sacrificed at study end on day 21. There was no mortality, and, except on the day of dosing when the entire test material group showed reduced motor activity and dyspnea, all animals appeared normal throughout the study. Tissue samples were evaluated for *Aureobasidium pullulans* after sacrifice. The following tissues were negative for *Aureobasidium pullulans* at all time points: Feces, brain, kidney, and intestine. Blood samples were negative except for one male on day 0; lung samples were negative except for two males and two females on day 0; liver samples were negative except for three males on day 0; spleen samples were negative except for two males on day 0; lymph node samples were negative except for one animal on day 7, and stomach samples were negative except for two males on day 0. These findings show a pattern of clearance with no *Aureobasidium pullulans* DSM 14941 detected by day 14. The results of this acceptable study demonstrated that *Aureobasidium pullulans* DSM 14941 was not toxic, infective, and/or pathogenic in rat, when dosed at  $0.8 \times 10^8$  cfu/animal.

3. *Acute Injection Toxicity/Pathogenicity (OCSPP Guideline 885.3200; MRID No. 47871807 and 47871808)*. In an acute subcutaneous toxicity/pathogenicity study (MRID 47871807), male and female rats were injected with *Aureobasidium pullulans* strain DSM 14940 ( $2.36 \times 10^{10}$  cfu/g) and DSM 14941 ( $1.5 \times 10^{10}$  cfu/g). Interim sacrifices were made on days 3, 7, and 14; the remaining animals were sacrificed at test end on day 21. There were no deaths, and all animals appeared normal throughout the study except for edema or slight erythema at the injection site. Samples of the following tissues were negative for *Aureobasidium pullulans* at all time points: Feces, blood, brain, lung, liver, kidney, spleen, stomach, and intestine. Lymph node samples were negative except for one animal sacrificed on day 7. The study author suggested this was likely a post-mortem transmission. A pattern of clearance was observed in this study, with no *Aureobasidium pullulans* DSM 14941 or 14940 detected by day 14. The results of this acceptable study demonstrated that *Aureobasidium pullulans* strains DSMZ 14940 and DSMZ 14941 were not toxic, infective, and/or pathogenic in rats, when dosed at  $1.95 \times 10^7$  or  $1.12 \times 10^7$  cfu/animal, respectively.

In a second acute subcutaneous toxicity/pathogenicity study (MRID 47871808), male and female rats were injected with *Aureobasidium pullulans* strain DSM 14941 ( $1.1 \times 10^9$  cfu/g). Interim sacrifices were made on days 1 and 7; the remaining animals were

sacrificed at test end on day 21. There were no deaths, and all animals appeared normal throughout the study except for severe edema or slight erythema at the injection site. Samples of the following tissues were negative for *Aureobasidium pullulans* at all time points: Brain, lung, spleen, kidney, lymph nodes, blood and urine. The skin was positive for *Aureobasidium pullulans* in three males and three females from the test material group on day 1 and in two females of the same group on day 7. The liver of one male from the test material group was positive on day 1. The cecum contents were positive in one male and one female from the test material group on day 1 and in two females from the same group on day 7. These findings show a pattern of clearance with no *Aureobasidium pullulans* DSM 14941 detected by day 21. The results of this acceptable study demonstrated that *Aureobasidium pullulans* DSM 14941 was not toxic, infective, and/or pathogenic in rats, when dosed at  $1.6 \times 10^7$  cfu/animal.

4. *Acute Dermal Toxicity (OCSPP Guideline 870.1200; MRID 47869615)*. In an acute dermal toxicity study, the shaved skin of 10 rats was dosed with 2,000 milligram/kilogram (mg/kg) Blossom Protect ( $7 \times 10^9$  cfu/g each of strains DSM 14940 and DSM 14941) for 24 hours. One male exhibited chromodacryorrhea from day 7 to day 14 and one female exhibited chromodacryorrhea from day 1 to day 2 of the study, but this was not considered to be toxicologically significant because this is a normal but rare response and it did not result in mortality. All animals appeared healthy at necropsy. The lethal dose ( $LD_{50}$ ) was  $>2,000$  mg/kg. This study was rated acceptable, and the end use product (EP) is classified as toxicity category IV.

5. *Primary Dermal Irritation (OCSPP Guideline 870.2500; MRID 47869619)*. In a dermal irritation study, the shaved skin of 3 rabbits was dosed with 0.5 g Blossom Protect ( $7 \times 10^9$  cfu/g *Aureobasidium pullulans* strain DSM 14940 and  $7 \times 10^9$  cfu/g *Aureobasidium pullulans* strain DSM 14941) moistened with 1.0 milliliter (mL) deionized water for 4 hours. All animals appeared normal throughout the study; thus, Blossom Protect was considered to be non-irritating. This study was rated acceptable, and the EP is classified as toxicity category IV.

6. *Acute Oral Toxicity (OCSPP Guideline 870.1100; MRID No. 47869614)*. In an acute oral toxicity study, six animals received a single 2,000 mg/kg body weight (bw) dose of Blossom Protect 22% ( $2 \times 10^{10}$  cfu/g) *Aureobasidium pullulans* strain DSM



14940, 22% ( $2 \times 10^{10}$  cfu/g) *Aureobasidium pullulans* strain DSM 14941, 25% sucrose, 6% water. There was no mortality, and all animals appeared normal throughout the study. The LD<sub>50</sub> was >2,000 mg/kg. This study was rated acceptable, and the EP is classified as toxicity category III.

7. *Acute Inhalation Toxicity (OCSP Guideline 870.1300; MRID 47869617)*. In an acute inhalation toxicity study, 10 animals were exposed nose-only to a 10% suspension of Blossom Protect ( $7 \times 10^9$  cfu/g *A. pullulans* strain DSM 14940 and  $7 \times 10^9$  cfu/g *A. pullulans* strain DSM 14941) at 5.17 milligrams per liter (mg/L). The Mass Medium Aerodynamic Diameter (MMAD) was 4.2  $\mu$ m. There were no deaths and all animals appeared healthy throughout the study. Necropsy was unremarkable. The lethal concentration (LC<sub>50</sub>) was >5.17 mg/L. This study was rated acceptable, and the EP is classified as toxicity category IV.

8. *Acute Eye Irritation (OCSP Guideline 870.2400; MRID 47869618)*. In an eye irritation study, three rabbits were dosed with 0.1 mL (60-62 grams (g) of Blossom Protect ( $7 \times 10^9$  cfu/g *A. pullulans* strain DSM 14940 and  $7 \times 10^9$  cfu/g *A. pullulans* strain DSM 14941). One animal had a score of 1 for conjunctival redness 1 hour after application. There were no other clinical signs, and all animals appeared normal at 24 hours. Blossom protect was considered to be virtually non-irritating. This study was rated acceptable, and the EP is classified as toxicity category IV.

9. *In vivo Micronucleus Assay (MRID 47899304)*. Twenty mice (two groups of five male and two groups of five female mice) received single 2,000 mg/kg *Aureobasidium pullulans* strain DSM 14941 dissolved in water by oral gavage. There were no clinical signs observed in any of the test animals, which were sacrificed 24 or 48 hours after receiving the test material. The femoral bone marrow was immediately harvested, and the ratio of polychromatic erythrocytes to total erythrocytes (mature and immature) was determined, and 2,000 immature erythrocytes/animal were scored for the presence of micronucleated immature erythrocytes, a sign of potential toxicity or damage to genetic material in the cells. *Aureobasidium pullulans* strain DSM 14941 did not produce a statistically significant increase in micronucleated immature erythrocytes compared to the untreated control animals. The response of the positive control animals (treated with a known toxic substance, cyclophosphamide, by intraperitoneal injection, at

10 mg/kg) was appropriate for comparison and did produce a statistically significant increase in micronucleated immature erythrocytes compared to the untreated control animals. This study was rated acceptable.

10. *Influence of Temperature on Reproduction (MRID 47871833).*

*Aureobasidium pullulans* strain CBS 626.85 was isolated from the peritoneal dialysis fluid of a human in Australia. The effects of temperature on the reproduction or growth of *Aureobasidium pullulans* strains DSM 14940 and, DSM 14941, in liquid culture or on agar plates were examined and compared against this positive control, *Aureobasidium pullulans* strain CBS 626.85, to observe the ability of these strains to reproduce at human body temperature of 37 °C. All three strains grew well at 30 °C. At 33 °C, the number of replications (per 48 hours) of the *Aureobasidium pullulans* strains DSM 14940 and, DSM 14941 was less than one, while the number of duplications for strain CBS 626.85 was approximately five. Neither strain DSM 14940 or strain DSM 14941 was able to grow at 35 °C or 37 °C, while strain CBS 625.85 replicated (approximately) twice at 35 °C and once at 37 °C. Based on the lack of growth of the DSM strains at 35 °C and above, and given human body temperature is 37 °C, *Aureobasidium pullulan* strains DSM 14940 and DSM 14941 are expected to be non-pathogenic in humans. This study was rated acceptable.

11. *Hypersensitivity Incidents (OCSPP Guideline 885.3400; MRID No. 47945023).* No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals during research, development, or testing of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 were reported by the applicant. Any future hypersensitivity incidents must be reported per OCSPP Guideline 885.3400.

#### **IV. Aggregate Exposures**

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

##### *A. Dietary Exposure*

Should this microbial pesticide be present on food, the acute toxicity, infectivity, and pathogenicity data, as well as the data demonstrating the lack of growth at human body temperature submitted for *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 demonstrated that no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level resulting from application of these two proposed pesticide active ingredients in accordance with good agricultural practices (see Unit III.B.).

1. *Food.* Naturally occurring *Aureobasidium pullulans* is likely to be present on fresh produce. According to Webb and Mundt (1978) (Ref. 11) *Aureobasidium pullulans* is “a major resident on most green plants.” In a study with several species of crop plants, they determined *Aureobasidium pullulans* to be among the most abundant (71% - 85%) of all fungi present on the plant surfaces. *Aureobasidium pullulans* made up an average of 77.1% of the mold species isolated on green beans, and occurred at high levels (up to  $2.7 \times 10^4$  cfu/centimeter<sup>2</sup> (cm<sup>2</sup>)) on certain fruits (cucumbers and squash). Dietary exposure to *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, therefore, is possible from strawberries, grapes, pome and stone fruits harvested naturally and from plants treated with these fungicidal active ingredients. The submitted acute oral toxicity/pathogenicity studies indicated that if *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are ingested, no toxic or pathogenic effects will result. In addition, *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 do not reproduce at the normal human body temperature of 37 °C. Therefore, in the event oral exposure should occur by ingesting treated fruits, the Agency concludes that there is a reasonable certainty that no harm will result from exposure to such residues.

2. *Drinking water exposure.* Naturally occurring *Aureobasidium pullulans* is ubiquitous and has been isolated from all types of water (Ref. 14). Exposure of humans to residues of pesticides containing *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in consumed drinking water is possible but potential exposure through drinking water is reduced, given the proposed use patterns, use sites, and application methods for *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, which do not include direct application to aquatic environments. In the event that *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are transferred to surface water or ground water intended for human consumption, the fungi would not survive the high

temperatures, chlorination, pH adjustments, and/or filtration water is subjected to in a drinking water treatment facility. Even if oral exposure should occur through consumed drinking water, there is a reasonable certainty that no harm will result from exposure to such residues, based upon the lack of toxicity, infectivity, and/or pathogenicity, as well as the inability of these fungal strains to grow at human body temperature, demonstrated in the previously described toxicological studies (see Unit III.B.).

#### *B. Other Non-Occupational Exposure*

The use sites for these products include residential garden sites and agricultural sites. *Aureobasidium pullulans* is naturally present in many habitats, and based on the data and other information submitted to satisfy data requirements for registration of the MPs and EPs containing the active ingredients *Aureobasidium pullulans* strains DSM 14940 and DSM 14941, no toxicity, infectivity, pathogenicity or other adverse effects from non-occupational exposure are expected (see Unit III.B.).

### **V. Cumulative Effects from Substances with a Common Mechanism of Toxicity**

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

The likelihood of adverse cumulative effects occurring via a common mechanism of toxicity is minimal, based on the lack of toxicity/pathogenicity/infectivity potential of the active ingredients when *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are used in or on food commodities and/or labeled for residential uses (see Unit III.B.). In addition, *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 do not appear to produce a toxic metabolite produced by other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

### **VI. Determination of Safety for U.S. Population, Infants and Children**

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative

effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data summarized in Unit III.B., EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 do not demonstrate toxic, pathogenic, and/or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, the Agency has concluded that an additional margin of safety for infants and children is unnecessary in this instance. Further, the need to consider consumption patterns, special susceptibility, and cumulative effects does not arise when dealing with pesticides with no demonstrated significant adverse effects.

## **VII. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA

section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Aureobasidium pullulans* strains DSM 14940 or DSM 14941.

### **VIII. Conclusions**

EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941. Therefore, an exemption from the requirement of a tolerance is established for residues of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in or on all food commodities when applied as a preharvest fungicide and used in accordance with good agricultural practices.

### **IX. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

## **X. References**

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9. Slavikova, E., R. Vadkertiova, and D. Vranova. 2007. Yeasts colonizing the leaf surfaces. *J. Basic Microbiol.* 47: 344-350.
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12. Kockova-Kratochvilova, A., M. Cernakova, and E. Slavikova. 1980. Morphological changes during the life cycle of *Aureobasidium pullulans* (de Bary) Arnaud. *Folia Microbiologica*, 25.
13. U.S. EPA. December 2011. DRAFT Biopesticides Registration Action Document of *Aureobasidium pullulans* strains DSM 14940 and 14941
14. Slavikova, E. and R. Vadkertiova. 1997. Seasonal occurrence of yeasts and yeast like organisms in the river Danube. *Antonie van Leeuwenhoek* 72: 77–80, 1997.

## **XI. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).



**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 30, 2012.

Steven Bradbury,

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1312 is added to subpart D to read as follows:

**§ 180.1312 *Aureobasidium pullulans* strains DSM 14940 and DSM 14941; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of the microbial pesticides, *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in or on all food commodities when applied preharvest and used in accordance with good agricultural practices.